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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Patent No. 5,847,170
IPR2016-00627

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 5,847,170

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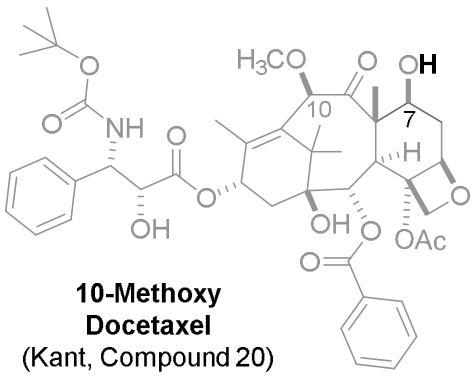
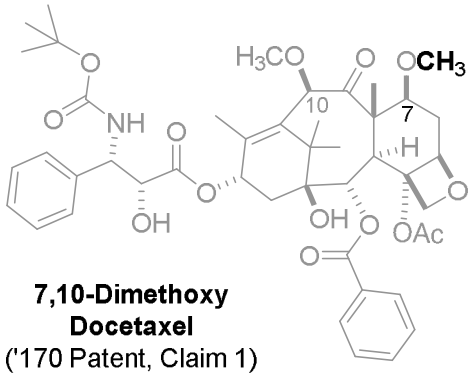
I. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 311 and § 6 of the Leahy-Smith America Invents Act ("AIA"), and to 37 C.F.R. Part 42, Mylan Laboratories Limited, ("Petitioner") requests review of United States Patent No. 5,847,170 to Bouchard *et al*. ("the '170 patent," Ex. 1001) that issued on December 8, 1998, and is currently assigned to Aventis Pharma S.A. ("Patent Owner"). This Petition demonstrates, by a preponderance of the evidence, that there is a reasonable likelihood that claims 1 and 2 of the '170 patent are unpatentable for failing to distinguish over prior art.

The claimed anti-cancer compound, 4α-acetoxy-2α-benzoyloxy-5β,20-epoxy-1β-hydroxy-7β,10β-dimethoxy-9-oxo-11-taxen-13α-yl(2*R*,3*S*)-3-*tert*-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, referred to herein as 7,10-dimethoxy docetaxel, which subsequently became known as "cabazitaxel," differs from the well-known prior art anti-cancer drug docetaxel (Taxotere®) only by methylation at the C-7 and C-10 hydroxyls. At the time of the earliest claimed priority date, however, substitution (including simultaneous substitution) of docetaxel at each of these positions was known. In fact, methylation at each of the C-10 and C-7 hydroxyls was known in the art to increase the potency of docetaxel analogues. An exemplary prior art compound is shown below adjacent to the claimed compound. As shown in bold, the only difference between the two is the methyl group on the C-7 hydroxyl.



10-Methoxy Docetaxel
(Kant, Compound 20)



7,10-Dimethoxy Docetaxel
('170 Patent, Claim 1)

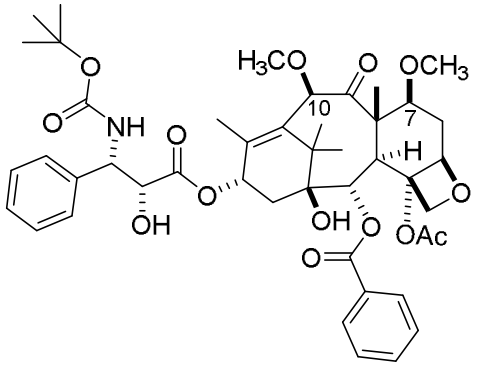
The prior art provides an analogue of docetaxel methylated at position C-10 having potent activity against cancer cells. The prior art also teaches the C-7 hydroxyl is available for substitution, and that a methoxy group at C-7 yields a compound with potent activity against cancer cells. The evidence and detailed explanation provided in this Petition establish that one of ordinary skill in the art would have had good reason to combine these teachings and produce an improved docetaxel analogue as recited in claims 1 and 2, *i.e.*, 7,10-dimethoxy docetaxel, and would have done so with a reasonable expectation of success in synthesizing thereby a compound with improved potency, a simpler synthetic pathway, and improved lipophilicity.

A. Brief Overview of the '170 Patent

The '170 patent is entitled "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them." In a general sense, the '170 patent is directed to the compound 7,10-dimethoxy docetaxel and its pharmaceutical compositions and methods of making it. The compound is said to find use in the inhibition of abnormal cell proliferation. Ex. 1001, col. 26, ll. 32-36. Independent claim 1 recites a single compound as follows:

1. 4α-Acetoxy-2α-benzoyloxy-5β,20-epoxy-1β-hydroxy-7β,10β-dimethoxy-9-oxo-11-taxen-13α-yl(2R,3S)-3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate.

The structure of 7,10-dimethoxy docetaxel is shown below:



Dependent claim 2 recites a pharmaceutical composition as follows:

2. A pharmaceutical composition comprising at least the product according to claim 1 in combination with one or more pharmaceutically acceptable diluents or adjuvants and optionally one or more compatible and pharmacologically active compounds.

B. Brief Overview of the Prosecution History

U.S. Patent Application 622,011 was filed on March 26, 1996, and issued on December 8, 1998, as U.S. Patent No. 5,847,170. Its earliest claimed priority date, to French Patent Application No. 95 03545, is March 27, 1995.

Prosecution focused on whether or not the methyl groups added to the C-7 and C-10 hydroxyls on the claimed 7,10-dimethoxy docetaxel constituted protecting groups. Finding that they were, the examiner rejected the claims, citing a patent to Holton *et al.* (US Patent No. 5,229,526) under 35 U.S.C. § 102(b). Ex. 1004 at 00697-00701. The examiner relied on Holton for teaching functionalization of the C-7 and C-10 positions of analogous taxanes with

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